

OFFICE ACTION RESPONSE
Serial No. 10/612,079
Docket No. ORW01-GN003

REMARKS

Introductory Comments

Claims 41-46, 48-76, and 105 are pending in the present application. Reconsideration of the application is respectfully requested.

Instant Office Action

Claim Objections

Claims 41, 63, and 105 stand objected to as allegedly including certain informalities. In particular, the Office action asserts that Applicant's use of "approximate" should be changed to "proximate." This ground of objection is respectfully traversed as Applicant's use of "approximate" is no less proper than a recitation of "proximate."

"Approximate" is an adjective that is commonly defined by numerous dictionaries as meaning near or very close.^{1,2} On the other hand, "proximate" is an adjective that is commonly defined by numerous dictionaries as meaning close to or very near.^{3,4} In view of the common English language usage of both words, there is no reason why utilization of "approximate" in the context of claims 41, 63, and 105 would be improper, but "proximate" would be proper. Thus, Applicant has declined to amend the implicated claims.

Reconsideration and withdrawal of the objections pertaining to claims 41, 63, and 105 are respectfully requested.

Claim Rejections – 35 U.S.C. § 112

Claims 63-76 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as his invention. This ground of rejection is respectfully traversed.

¹ See *Random House Unabridged Dictionary*, © Random House, Inc. 2006, definition of "approximate."

² See *Merriam-Webster's Collegiate® Dictionary, Eleventh Edition*, definition of "approximate."

³ See *Random House Unabridged Dictionary*, © Random House, Inc. 2006, definition of "proximate."

⁴ See *Merriam-Webster's Collegiate® Dictionary, Eleventh Edition*, definition of "proximate."

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The Office action first alleges that Applicant's claim 63 is confusing in light of the phrase "a lining mounted to at least one of the stabilizing post and an inner surface of the femoral component at least partially defining the prosthetic intercondylar channel, and remote from native connective tissue." Instead, the Office action suggests rewording the claim to recite the structure claimed. Applicant respectfully asserts that a structure is claimed that is not confusing in view of the specification.

Claim 63 recites: (a) a femoral component to be mounted to a patient's femur; (b) a tibial component to be mounted to the patient's tibia, the tibial component including a stabilizing post at its proximal end to be received within a prosthetic intercondylar channel of the femoral component to form a prosthetic hinge-type joint coupling; and (c) a lining mounted to at least one of the stabilizing post and an inner surface of the femoral component at least partially defining the prosthetic intercondylar channel, and remote from native connective tissue, to, at least temporarily, supplement periarticular stability between the stabilizing post and the prosthetic intercondylar channel, where the lining comprises a biologically reabsorbable lining material.

Applicant has clearly recited the structural components, as well as where the lining is mounted to either or both the tibial component and the femoral component. The distinction between the prior art cited in previous Office actions and Applicant's claims includes where the lining is mounted. As discussed in Applicant's prior response, when biologically reabsorbable materials are mounted to native tissue, the biologically reabsorbable materials transform into connective tissue or other native tissue, such as scar tissue. In direct contrast, Applicant's claims call out a structure where the biologically reabsorbable material is not mounted to native tissue at all (i.e., remote from native connective tissue), but rather is mounted to inert, foreign objects to be implanted into the body, where the lining is positioned on the implants remote from any native tissue upon implantation. The placement of the reabsorbable material on inert, foreign objects (such as polyethylene or titanium) results in the material being degraded without transforming into connective tissue or other native tissue. Thus, Applicant has recited a specific structure in claim 63 that is fully compliant with 35 U.S.C. § 112, second paragraph.

Reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph, rejections pertaining to claims 63-76 are respectfully requested.

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Claim 64, and each claim depending therefrom, is also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as his invention. This ground of rejection is respectfully traversed.

The Office action first alleges that Applicant's claim 64 is confusing in light of the phrase "further comprising at least one fastener for mounting the lining to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining the prosthetic intercondylar channel." The Office action alleges that the foregoing limitation is a run-on sentence without clear recitation of structure being claimed using alternate phraseology. But this conclusion does not accord with the language of claim 64.

Claim 64 recites, in part, "[t]he knee prosthesis of claim 63, further comprising at least one fastener for mounting the lining to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining the prosthetic intercondylar channel." The foregoing language clearly recites structure, in the form of fasteners, that are operative to mount the lining to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining the prosthetic intercondylar channel. This language is entirely consistent with the limitations of claim 63 that recite a lining mounted to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining the prosthetic intercondylar channel. In other words, at least one fastener is utilized to mount the lining to either (or both, presuming multiple fasteners and multiple linings are involved) the tibial component or the femoral component. It is respectfully submitted that the recitation of a "fastener" is a structural element. Thus, Applicant has recited a specific structure in claim 64 that is fully compliant with 35 U.S.C. § 112, second paragraph.

Reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph, rejections pertaining to claim 64, and those claims depending therefrom, are respectfully requested.

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Claim Rejections – 35 U.S.C. § 102

Claims 41-46, 48-54, and 60 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,592,622 to Ferguson ("Ferguson"). This ground of rejection is respectfully traversed.

In the June 27 Office action, the Examiner asserts that the "band assembly" of Ferguson "is capable of being mounted to at least one of a tibial component 10 so that the lining is between the tibial component and a femoral component and approximate a prosthetic intercondylar channel."⁵ But the assertions of the Office action by themselves prove that Ferguson does not anticipate Applicant's claims 41-46, 48-54, and 60, principally because the Office action relies on Ferguson being "*capable of*," rather than citing to what Ferguson actually discloses.^{6,7} It is well established that *more* is required than a prior art structure be "*capable of*" what is claimed to qualify as an anticipatory reference. Rather, what is required for anticipation is that the disclosure place those skilled in the art in possession of what Applicant claims.⁸ Ferguson clearly does not do this. If it did, there would be no need for reliance on what Ferguson "*is capable of*."

Applicant's claim 41 also recites that the lining is mounted remote from native connective tissue. The Office action asserts that Applicant's limitation of "remote from native connective tissue" only requires the lining to be "situated at some distance" from native connective tissue.⁹ Presuming this is true, Ferguson still does not satisfy such a limitation.

The Office action incorrectly asserts that Ferguson discloses an embodiment reading on Applicant's claims. However, in actuality, exactly the opposite is true. The Examiner alleges that "the band of resorbable material or 'lining 36' is positioned on the outside of band 34 making the lining remote from native connective tissue 30."¹⁰ But this

⁵ June 27, 2007 Office action, p. 3.

⁶ See M.P.E.P. § 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

⁷ See M.P.E.P. § 2131 "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

⁸ See *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (in order to anticipate, "the [prior art] reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it").

⁹ June 27, 2007 Office action, p. 6.

¹⁰ June 27, 2007 Office action, p. 6.

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statement is factually wrong, principally because band 36 of Ferguson is inside of band 34. Thus, Ferguson discloses precisely the opposite structure as asserted in the Office action. In other words, Ferguson actually discloses that the inner band 36 is constructed of a resorbable material and it is this band 36 that is in direct contact with the patellar ligament.¹¹ As such, it is beyond legitimate dispute that Ferguson fails to disclose a resorbable lining remote from native connective tissue, such as recited in claim 41. In view of the disclosure of Ferguson, Applicant's claim 41 stands in condition for allowance.

If the instant ground of rejection is sustained upon reconsideration by the Examiner, Applicant respectfully requests the Examiner cite to binding authority for the proposition that "capable of" is a sufficient basis for anticipation.

Reconsideration and withdrawal of the 35 U.S.C. § 102, rejections pertaining to claims 41-46, 48-54, and 60 are respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 41-46, 48-63, 65-76 and 105 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of U.S. Patent No. 5,571,193 to Kampner ("Kampner") in view of U.S. Patent No. 5,876,446 to Agrawal et al ("Agrawal"). This ground of rejection is respectfully traversed.

To render obvious claims 41-46, 48-63, 65-76 and 105, the Examiner is required to: (1) determine the scope and content of the prior art; (2) ascertain the differences between the prior art and the claims at issue; and (3) resolve the level of ordinary skill in the pertinent art. *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). Moreover, Kampner and Agrawal must: (1) provide a reasonable expectation of success; and (2) teach or suggest all the claim limitations. M.P.E.P. § 2143. In order to facilitate review, the Supreme Court admonished those sitting in judgment to explicitly state the rationale underlying the assertion of obviousness. *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007), citing *In re Kahn*, 441 F.3d 97, 988 (Fed. Cir. 2006). The Office action summarily rejects 25 separate claims in roughly one-half of a page without explicitly addressing any

¹¹ See U.S. Patent No. 6,592,622, Col. 5, ll. 1-35; FIGS. 2 & 3.

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of the prongs recited in *Graham* nor whether a reasonable expectation of success is present. For these reasons alone, this ground of rejection fails to comply with the standards set forth in *KSR* and is therefore improper.

The independent claims at issue, claims 41, 63, and 105, each include limitations not taught or suggested by Kampner and Agrawal. For example, claim 41 is directed to a knee prosthesis comprising: (a) a tibial component to be mounted to a patient's tibia; (b) a femoral component to be mounted to a patient's femur, and to be pivotally coupled to the tibial component to form a prosthetic knee joint; and (c) a lining mounted to at least one of the tibial component and the femoral component in the prosthetic knee joint, and remote from native connective tissue, so that the lining is between the tibial component and the femoral component approximate a prosthetic intercondylar channel of the femoral component to supplement periarticular stability between the tibial component and the femoral component, where the lining comprises a biologically reabsorbable lining material. It is respectfully submitted that neither Kampner nor Agrawal discloses a biologically reabsorbable lining, remote from native connective tissue, positioned between the tibial component and the femoral component approximate a prosthetic intercondylar channel of the femoral component. For this reason alone, the 35 U.S.C. § 103(a) ground of rejection should be withdrawn.

The Office action glosses over the deficiencies of Kampner and Agrawal by improperly alleging that those skilled in the art would have combined these references to reach Applicant's claimed invention. But the fact remains that all of the claim limitations must be taught or suggested by the prior art.¹² This requirement is clearly absent from the combination of Kampner and Agrawal. The absence of Applicant's claimed features in this prior art combination is consistent with an invention that is novel and nonobvious. Applicant can only presume a misunderstanding exists that has to date inhibited allowance of these pending claims.

¹² See M.P.E.P. § 2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).")

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The rationale supporting the Office action conclusion that Kampner combined with Agrawal renders obvious Applicant's claims evidences a misunderstanding of the claimed invention or a misunderstanding of what Kampner and Agrawal disclose. The Office action itself summarizes Agrawal as disclosing "a coating or a lining on the tissue-mating surfaces of a prosthetic joint for enhancing bio-fixation."¹³ The Office action then hypothesizes that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a lining as taught by Agrawal et al. on the inner surface of the Kampner femoral component to enhance bio-fixation of the femoral component."¹⁴ This hypothesis, respectfully, makes no sense.

Bio-fixation in the context of Agrawal refers to the ability of the implant to bond to the native tissue and be substantially fixed in position (i.e., immovable). Thus, Agrawal was concerned with bonding the hip joint implant to native bone (femur) to secure the implant in place. It should be noted that at no time is the coating of Agrawal either between prosthetic components or remote from connective tissue (including bone, in this case). Applicant's claimed invention does not pertain to bio-fixation and, even if it did, the alleged Kampner-Agrawal combination would not result in an embodiment reading on Applicant's claims.

Each of Applicant's independent claims, claims 41, 63, and 105, includes a limitation clearly distinguishable from the Kampner-Agrawal combination by way of the lining being remote from connective tissue or that repositioning or degradation of the lining does not appreciably hinder the functionality of the femoral component and the tibial component. These limitations make clear that Applicant's claimed lining simply degrades and goes away, without the lining being replaced with scar or natural connective tissue. Applicant analogizes his claimed lining to a bushing that reduces play, but allows for gradual increases in play as the native tissue stabilizing the joint heals post surgery. In this fashion, the lining mounted between two prosthetic components would simply erode over time and result in empty space between the components. Applicant's result, however, is almost exactly the opposite of what Agrawal discloses.

¹³ June 27, 2007 Office action, p. 4.

¹⁴ June 27, 2007 Office action, p. 4.

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Even if one skilled in the art would combine Agrawal with Kampner, the resulting embodiment, at best, would be a PLA coating on the stems of the femoral and tibial implants to secure these components within the longitudinal tibial and femoral bone cavities. In other words, the combination would not result in any embodiment having a lining either between prosthetic components or remote from connective tissue as recited by Applicant's claims. Presuming, only for arguments sake, that the alleged combination would somehow lead to using PLA between the femoral and tibial components, the proposed modification would impermissibly change the principal of operation of the embodiments of Kampner.

Simply put, the prior art method of operation of Kampner would significantly change if combined with Agrawal. M.P.E.P. § 2143.02 provides in relevant part:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (C.C.P.A. 1959).

It is clear that a coating, as recited by Agrawal, would significantly change the operation of Kampner's prosthetic knee joint. This is clear, particularly in view of the fact that Kampner itself discloses using resorbables, but does so contravening the disclosure of Agrawal.^{15,16} Interestingly, Kampner discloses "resorbables" that coat the femoral and tibial stems, with the resorbables allegedly going away to provide free floating inner cores, which Kampner teaches is advantageous to obviate any abnormal stress transfer to the bones.¹⁷ In direct contrast, Agrawal discloses using a PLA coating to facilitate bone in-growth for the prosthetic implant. In other words, if the PLA coating of Agrawal was used in place of the resorbables of Kampner, bone in-growth would result, thereby creating abnormal stress transfers as a result of the inner cores not being free floating, something Kampner teaches away from practicing.

If a proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed

¹⁵ U.S. Patent No. 5,571,193, Col. 9, ll. 15-47.

¹⁶ U.S. Patent No. 5,571,193, Col. 10, ll. 15-47.

¹⁷ U.S. Patent No. 5,571,193, Col. 10, ll. 35-39.

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modification.¹⁸ In this case, the PLA of Agrawal is not intended to simply go away, but is rather intended to facilitate bone in-growth to secure the prosthetic implant. This result would clearly provide an embodiment that Kampner itself teaches away from. Thus, the recited rationale in the Office action for combining Kampner with Agrawal is not objectively logical and would appear to be impermissible hindsight. On this ground alone, the rejection of claims 41-46, 48-63, 65-76 and 105 under 35 U.S.C. § 103(a) is untenable.

In view of the foregoing, the combination of Kampner with Agrawal fails to disclose each and every one of the claims limitations. Moreover, even if Kampner and Agrawal disclosed all of Applicant's claimed limitations, the combination of these references is belied by the fabrication of an embodiment unsatisfactory for its intended purpose as the references themselves teach away from such a combination. Reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of record for claims 41-46, 48-63, 65-76 and 105 are respectfully requested.

Claims 55, 56, 58, 59, 61, and 62 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,592,622 to Ferguson ("Ferguson") in view of U.S. Patent No. 6,616,698 to Scarborough ("Scarborough"). This ground of rejection is respectfully traversed.

Claim 41 recites, in part, a lining mounted to at least one of the tibial component and the femoral component in the prosthetic knee joint, and remote from native connective tissue, so that the lining is between the tibial component and the femoral component approximate a prosthetic intercondylar channel of the femoral component to supplement periarticular stability between the tibial component and the femoral component. In other words, the lining is not mounted to native connective tissue, such as bone. As discussed with respect to the 35 U.S.C. § 102(e) rejections of Applicant's claims in view of Ferguson, the Examiner is mistaken as to what Ferguson discloses. Namely, Ferguson only discloses, in the context of a resorbable material, positioning the resorbable material in contact with native tissue. In direct contrast, Applicant's claims recite a lining remote from native connective tissue. Thus, the conclusion of the Office

¹⁸ See M.P.E.P. § 2143.01, Section V, citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

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action that Ferguson discloses each of the claim limitations of claims 55, 56, 58, 59, 61, and 62 is clearly in err.

Scarborough, incidentally, is cited in the Office action for the proposition that "[i]t is very well known to use gentamicin as an antibiotic and osteogenic materials such as stem cells and transforming growth factors in implants as evidenced by Scarborough."¹⁹ More importantly, however, is whether Scarborough discloses using such materials in linings that are not connected to native tissue. The answer to this question is resoundingly, NO. The overriding principal of all of the art cited to date and amalgamated is that those skilled in the art were unaware of using a resorbable lining to temporarily decrease play. In almost every prior art reference cited by the Examiner during prosecution, the reference teaches generally the same theme, use of resorbables to promote connective tissue growth (ligaments, tendons, or bone). Those disclosures are, however, entirely at odds with Applicant's claims.

The mere fact that Ferguson could be modified does not render obvious Applicant's claims unless Ferguson also suggests the desirability of the combination.²⁰ Although it may be alleged that Ferguson is capable of being modified to construct an embodiment reading on Applicant's claims, one skilled in the art must also be motivated to do so. But those skilled in the art would not have been motivated to modify Ferguson to read on Applicant's claims. If anything, Ferguson teaches away from Applicant's claims.

Those portions of Ferguson cited to by the Examiner teach a structure entirely at odds with the structure claimed by Applicant. Ferguson teaches using a resorbable material connected to a patient's native connective tissue to spur on native connective tissue growth that connects bone to the tibial prosthetic component.²¹ But Applicant is not at all interested in forming connective tissue that couples soft tissue to a prosthetic component. If anything, Applicant wants to avoid coupling soft tissue between joints to prosthetic components. Ferguson, on the other hand, is directed to the exact opposite situation and teaches those skilled in the art to use resorbable materials to form bridges that are mounted to connective tissue and transform into soft tissue connecting to certain

¹⁹ June 27, 2007 Office action, p. 5.

²⁰ See M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

²¹ See U.S. Patent No. 6,592,622 at column 5, lines 1-59.

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prosthetic components.²² In this regard, Ferguson, if anything, clearly teaches away from Applicant's claims.

The sole rebuttal to Applicant's arguments was the recitation in the June 27 Office action that Ferguson does disclose a resorbable remote from connective tissue. But Applicant has shown this conclusion to be a misunderstanding of what Ferguson discloses, as the inner band 36 of Ferguson is constructed of a resorbable material and it is this band 36 that is in direct contact with the patellar ligament.²³ Therefore, Ferguson does not disclose a resorbable lining remote from connective tissue. In view of the foregoing, it is respectfully submitted that Applicant's claims are novel and nonobvious in view of the prior art of record.

Reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejections of record over Ferguson in combination with Scarborough for claims 55, 56, 58, 59, 61, and 62 are respectfully requested.

Allowable Subject Matter

Applicant acknowledges the determination that claim 64 is allowable. In light of the grounds of rejection recited in the Office action and the due consideration the Examiner will give to Applicant's remarks, Applicant has refrained from prematurely rewriting this claim in independent form.

Possible Telephone Interview

Applicant has addressed the grounds of rejection in each of the foregoing Office actions, but it appears that the underlying grounds remain virtually unchanged even in view of Applicant's remarks calling into question the merits of the rejections. In view of the grounds of rejection and nexus that the cited prior art has (virtually all dealing with connective tissue regrowth between a prosthetic and native tissue), Applicant invites the Examiner to telephone the undersigned to possibly schedule a telephone interview so that all substantive issues can be clearly defined for any further prosecution on the merits. In

²² See U.S. Patent No. 6,592,622 at column 1, lines 7-9, TECHNICAL FIELD OF THE INVENTION section, "The present invention relates generally to a prosthesis, and more particularly to an apparatus and method for securing soft tissue to an artificial prosthesis."

²³ See U.S. Patent No. 6,592,622, Col. 5, ll. 1-35; FIGS. 2 & 3.

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this manner, it is hoped Applicant and the Examiner can agree on the allowance of the instant claims.

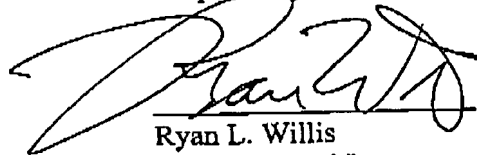
Conclusion

In light of the foregoing, it is respectfully submitted that claims 41-46, 48-76, and 105, now pending, are patentably distinct from the references cited and are in condition for allowance. Reconsideration and withdrawal of the rejections of record are respectfully requested.

The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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